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10/705,403	11/10/2003	Satoshi Mizutani	20050/0200484-US0	4411	
	7278 7590 10/31/2008 DARBY & DARBY P.C.			EXAMINER	
P.O. BOX 770	tation	REICHLE, KARIN M			
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)			
	10/705,403	MIZUTANI ET AL.			
Office Action Summary	Examiner	Art Unit			
	Karin M. Reichle	3761			
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address			
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin	ATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).			
earned patent term adjustment. See 37 CFR 1.704(b).  Status					
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<ul> <li>1)  Responsive to communication(s) filed on 25 J</li> <li>2a) This action is FINAL. 2b) This</li> <li>3) Since this application is in condition for allowanclosed in accordance with the practice under E</li> </ul>	s action is non-final. nce except for formal matters, pro				
Disposition of Claims					
4) ☐ Claim(s) 1.5-7.9-14 and 18 is/are pending in the 4a) Of the above claim(s) is/are withdra 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1.5-7,9-14 and 18 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.				
Application Papers					
9)⊠ The specification is objected to by the Examine	er.				
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correct	•	•			
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached Office	Action or form PTO-152.			
Priority under 35 U.S.C. § 119					
<ul> <li>12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority document</li> <li>2. Certified copies of the priority document</li> <li>3. Copies of the certified copies of the priority application from the International Burea</li> <li>* See the attached detailed Office action for a list</li> </ul>	ts have been received. ts have been received in Applicati rity documents have been receive u (PCT Rule 17.2(a)).	on No ed in this National Stage			
Attach maget(a)					
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date  12/18/07 1/17/08 1/23/08 1/31/08 4/3/08 4/29/08 5/30/08 7/16/08	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate			



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#### **DETAILED ACTION**

#### Response to Amendment

1. Substitute specifications were filed 7-25-08 and 4-14-08 for consideration. The 7-25-08 specification shows all the changes shown in the 4-14-08 specification plus the addition of one paragraph, see Applicant's 7-25-08 remarks, rather than just the changes made to the 4-14-08 specification. However neither specification has been entered since not only do such not overcome all the previously pending objections, see paragraph 6 infra, but such also appear to introduce new matter. For example, see Exhibit I. Applicant states that the first and second paragraphs on page 8 of the marked up specification of 7-25-08 provide the support for the amendments at page 3, paragraph 2 and paragraph 19, paragraph 4 of such specification. However, paragraph 4 of page 19 discusses plurality of main bodies combined in a particular manner which is not what is set forth on page 8, first two paragraphs. Thus the specification filed 3-14-06, the claims filed 7-25-08 and the remarks filed 4-14-08 and 7-25-08 will be considered for the following action on the merits. Therefore, see paragraphs 3-5 infra.

#### **Specification**

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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For Example:

#### Description

3. The substitute specification including the abstract filed 7-25-08 and 4-14-08 has not been entered. Therefore see the following paragraphs.

- 4. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are: the abstract, the first sentence, page 22, lines 13-16.
- 5. The disclosure is objected to because of the following informalities: The specification is still replete with informalities. For example: 1) The Summary of the Invention section, i.e. **a description of the <u>claimed invention</u>**, not the detailed description of the invention, regardless of length, and the invention of the claims are still not commensurate in scope, see MPEP 608.01(d). It is noted the extraneous descriptive matter in the Summary should be included in the Detailed Description instead, if not already. 2) On page 4, line 13, the numeral in parenthesis should be deleted. This also applies to page 13, lines 14, 23 and 31. 3) On page 17, line 17 from the bottom line, "3" still should be --3(A)-(B)--. 4) A main body which <u>comprises</u> an elongated convex area formed in the longitudinal direction of the surface sheet so that the substantial center area of the mainsheet body is formed convex in the lateral direction is claimed in claim 1 on lines 18-21 and similarly claimed in claim 14. Such description requires the mainsheet body form such convex area. On lines 22-23 of claim 1 it is further described that at least an end of the convex area forms a finger insertion opening. While, e.g., page 6, paragraphs 3-5 of the 3-14-06

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specification and page 7, lines 17-page 8, line 4, and page 22, line 3-page 23, line 14 and Figures 1-4 of the originally filed specification describe that the finger insertion opening is formed between unbonded portions of a convex area defined by the center area of the main sheet body and the sub-sheet body, i.e. not by a convex portion of surface sheet, the third full paragraph of the 3-24-08 specification and the originally filed specification at page 4, lines 6-9 describe such a main body which comprises an elongated convex area formed in the longitudinal direction of the surface sheet so that the substantial center area of the surface sheet is formed convex in the lateral direction. Therefore, at the very least, the description of the convex portion and the opening defined thereby is not clear and consistent throughout the application. If such opening is formed between the bodies as already described, a complete, clear, consistent description of the invention should be set forth throughout the application. The specification should be carefully reviewed and revised, as necessary, to overcome all the informalities. Applicant is thanked in advance for the continuing cooperation in placing the specification in proper form.

Appropriate correction is required.

6. The amendment filed 3-14-06 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: referring to the marked-up specification, the amendments to pages 4, 6-8, 10, 12-15.

Applicant is required to cancel the new matter in the reply to this Office Action.

The amendments on those pages remove referral to a particular embodiment, i.e. (1), A interlabial pad according to (1), (3)...according to (1) or (2), (4)...according to (3), so that the

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combinations described originally in the Summary are no longer described in that section in the same scope. For example, the bonding set forth in the third full paragraph of page 4 is no longer described as being in combination with the pad as set forth in the third full paragraph of page 3 but rather just "an interlabial pad". If Applicant maintains such language the portion of the original specification which provides support for each of the combinations of the same scope as now described in a single embodiment should be set forth.

### Claim Language Interpretation

7. The claim terminology is interpreted in light of the specific definitions on page 5, lines 10-11 and the sentence bridging pages 6-7. Any other claim language not specifically defined has been interpreted in view of the usual and common meaning of such, i.e. the dictionary definition. It is noted that the terminology "bonded" without any modifying terminology includes indirect bonding or direct bonding. A product by process is recited by line 2 of claim 6, i.e. see MPEP 2113, i.e. patentability is determined based on the end product of a product by process claim, not the process. The end product of claim 6 is interpreted to include a portion of the main sheet body being bent. It is noted that the terminology "mini" in claims 5 and 18 has not been claimed with respect to any other structure, i.e. mini compared to what, and thereby is considered relative absent specific dimensions thereof. See also prior art rejections infra.

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#### Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 5-7, and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hammons PCT '572.

Claim 1: See Claim Language Interpretation, hereinafter also referred to as CLI, and '272 at the Figures, esp., 1-2, 4-7, 36, and 45, page 4, third full paragraph, page 12, second paragraph, page 13, sixth to last line -page 14, last line, the paragraph bridging pages 16-17, page 17, last paragraph, page 18, first two paragraphs, page 19, last two paragraphs, page 20, last full paragraph, page 22, second paragraph, page 23, second and third full paragraphs, page 38, second full paragraph, and page 59, third full paragraph, i.e. '572 teaches an interlabial pad comprising a main sheet body 22 comprising a water permeable surface sheet facing a body side, e.g. 156 in Figure 45 and last paragraph on page 48, and a water permeable backing sheet, e.g. 122 in Figure 45, facing a garment side opposite to the body side, see Figures, the surface sheet and the backing sheet enclosing a first absorber 122 for absorbing body fluid, wherein the surface sheet and the backing sheet of the main sheet body each have longitudinal side edges at opposite ends in the lateral direction, each of the longitudinal side edges of the surface sheet being directly bonded to one of the longitudinal side edges of the backing sheet, see Figure 45 and page 50, second full paragraph, at a respective one of the opposite ends, and a substantially planar-shaped sub-sheet body 24 comprising a water permeable surface sheet 70 facing the body side and either a water permeable or non-permeable backing sheet, impervious sheet 72, facing the garment side, the surface sheet and the backing sheet enclosing a second absorber 74 for

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absorbing body fluid, wherein the surface sheet and the backing sheet of the sub-sheet body each have longitudinal side edges at opposite ends in the lateral direction, each of the longitudinal side edges of the surface sheet being directly bonded to one of the longitudinal side edges of the backing sheet, see, e.g., Figures 1-2, at a respective one of the opposite ends, wherein the main sheet body comprises an elongated convex area formed along a longitudinal direction of the main sheet body, see, e.g., Figure 2, adjacent lines L, L1, so that a substantial center area of the main sheet body in a lateral direction is formed convex towards the body side, wherein the elongated convex area has a hollow part, see, e.g., Figure 2 between 22 and 24 adjacent lines L, L1, with a substantially triangular shape in a lateral cross section, and two ends in the longitudinal direction, see, e.g., Figures 4-6, at least one of the two ends forming a opening into the hollow part, see again Figures 4-6 adjacent the ends, wherein the main sheet body and the sub-sheet body each have longitudinal side edges at opposite ends in the lateral direction, e.g., the edge respective sides of L, L1 (Note the claim does not require that the main body and sub-sheet bodies also have end edges at opposite ends in the longitudinal direction which separate the longitudinal side edges), each of the longitudinal side edges of the main sheet body being directly bonded to one of the longitudinal side edges of the sub-sheet body, see, e.g., Figure 1, at a respective one of the opposite ends, bonded at the edge on one side of L, L1 and bonded at the edge on the other side of L, L1 and see discussion of edges supra, wherein the main sheet body and the sub-sheet body are not directly bonded to each other, other than at each of the longitudinal side edges, see the first full paragraph on page 22 and the last two sentences of the second full paragraph of page 22 and note that the terminology "may also be" also infers "may also not be". Claim 1 also requires the opening be a finger insertion opening through which a finger is insertable into the hollow

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part, i.e. a function, capability or property of the opening. See not only the discussion of the structure supra but also infra, i.e. includes the claimed structure thereof. Therefore there is sufficient factual evidence for one to conclude that such opening of '272 also inherently includes such claimed functions, properties and capabilities, i.e. capable of having a finger inserted therein, see MPEP 2112.01. It is noted that the claim does not require the opening be an opening through which a finger is insertable parallel to the longitudinal direction of the main sheet body.

Claim 5: The interlabial pad further comprises a mini sheet piece fixed on the backing sheet of the sub-sheet body, facing the garment side, see, e.g., page 40, second and third full paragraphs, e.g. '094 incorporated thereby at the Figures, e.g. '094 at Figures 8A and 8E (Note the claim does not require a single piece or monolithically formed sheet) and also the paragraph bridging cols. 11-12 and col. 5, lines 1-6, and an insertion opening being formed between the backing sheet and the mini sheet piece, e.g. for receiving the crotch portion of the undergarment, wherein the mini-sheet piece has longitudinal side edges at opposite ends in the lateral direction, each of the longitudinal side edges of the mini sheet piece being bonded to one of the longitudinal side edges of the backing sheet at a respective one of the opposite ends, see again the Figures and portions of '094 and note that direct bonding is not required. This claim also requires the opening be a finger insertion opening, i.e. a function, capability or property of the opening. See not only the discussion of the structure supra but also infra, i.e. includes the claimed structure. Therefore there is sufficient factual evidence for one to conclude that such opening of '272 also inherently includes such claimed functions, properties and capabilities, i.e. capable of having a finger inserted therein, see MPEP 2112.01.

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Claim 6: The elongated convex area includes a bent portion formed by bending the main sheet body, see discussion of claim 1 and Figure 2.

Claim 7: The triangular shape of the elongated convex area, see claim 1, of the main sheet body has a top and a bottom, see, e.g., see Figures 1-2 and 7, the top being a vertex of the triangular shape and positioned closer to the body side, see already cited Figures as well as Figures 8A-B, wherein a longitudinal length at the top is shorter than a longitudinal length at the bottom, see Figures 1, 4, 6, 7, and wherein each of the two ends of the elongated convex area has an opening with edges that are inwardly sloped in relation to a direction perpendicular to the longitudinal direction of the surface sheet, from the bottom to the top of the triangular shape of the elongated convex area, see Figures 2 and 7.

Claim 10: The lateral cross sectional area of the elongated convex area continuously decreases as the area is taken from one end to the other end along the longitudinal direction, See Figures 5 and 32.

Claims 11-13: These claims require the interlabial pad be used together with a sanitary napkin, comprise an incontinent-interlabial pad for incontinence or comprise a vaginal-discharge interlabial pad for absorbing vaginal discharge, respectively, i.e. recite functions, properties or capabilities of the structure set forth in claim 1. If not already taught by the '272, see, e.g., the first full paragraph of page 10, at the very least '272 teaches such structure of claim 1. Therefore there is sufficient factual evidence for one to conclude that such same structure of '272 also inherently includes such claimed functions, properties and capabilities, see MPEP 2112.01. It is noted that claim 11 does not further require any further structure, i.e. a napkin

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Claim 14: See discussion of claim 1. Claim 1 additionally requires the interlabial pad is contained in the wrapping container for individual wrapping. See page 23, second and third full paragragraphs.

## Claim Rejections - 35 USC § 102/103

- 10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 11. Claim 9 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hammons et al '272.

Claim 9 requires the lateral cross sectional area of the elongated convex area be at least 1 cm2. See Figure 2, page 12, second full paragraph, page 21, last paragraph, page 16, second full paragraph Figure 45-47 and the paragraph bridging pages 49-50. Therefore, it is the Examiner's first position that at the very most '272 teaches the claimed cross-section with "sufficient specificity", see MPEP 2131.03 and, e.g., Figure 2 which shows cross-section of portion 34 alone includes is at least 4 thicknesses of absorbent, e.g. width is at least 8 mm, and is 25 mm in height, e.g. center portion alone has cross-sectional area of at least 1 cm2. In any case, see 2144.05. Therefore it is the Examiner's second position that since at the very least the claimed ranges "overlap or lie inside ranges disclosed by the prior art", In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); In re Woodruff, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990), or the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties, Titanium Metals Corp. of

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America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see discussion supra, a prima facie case of obviousness exists.

#### Claim Rejections - 35 USC § 103

- 12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 13. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammons et al '272.

Claim 18 requires a circumference inside the opening formed between the backing sheet of the sub-sheet body and the mini sheet piece be within a range of 40 mm to 80 mm. See again the portions of '272 recited with regard to claim 9, i.e. the length of 22 is between 50 and 100mm, the height of the opening is about that of the caliper of the lobes 36 and 38 and Figures 1 and 4-6, e.g., the opening circumference, i.e. '272 teaches a circumference of the opening which is at the very least close to that claimed (note the length of the opening is not as long as the length of the element 22). Therefore again a prima facie case of obviousness exists since, at the very least, although the claimed ranges and prior art ranges do not overlap they are close enough that one skilled in the art would have expected them to have the same properties, Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). See 2144.05 again.

### Response to Arguments

14. Applicant's remarks have been carefully considered but are either deemed moot in that the issues discussed have not been reraised or deemed not persuasive for the reasons set forth supra.

#### Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karin M. Reichle whose telephone number is (571) 272-4936. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Karin M. Reichle/ Primary Examiner, Art Unit 3761

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